

## REMARKS

### STATUS OF THE CLAIMS.

Claims 88, 90, and 92 are pending with entry of this amendment, claims 7, 8, 93, 97, 98, and 100-103 being cancelled herein. Claims 88, 90, and 92 are amended herein.

Under 37 C.F.R. § 1.116, amendments canceling claims may be entered after final rejection. In addition, § 1.116 states that amendments to the claims after final rejection may be entered if the amendments place the claims in better form for consideration on appeal. Applicants submit that the above amendments meet this criterion. The amendments to the pending claims are necessary to address a new rejection contained in the Final Office Action. Specifically, all previously pending claims were rejected under 35 U.S.C. § 112, first paragraph, on the ground that the specification allegedly fails to enable cyclic polypeptides. Applicants note that the claims pending prior to the first Office Action (dated October 21, 2003) read on cyclic polypeptides, and yet the claims were not rejected for lack of enablement on this ground in the first Office Action. Accordingly, the present Amendment is Applicants' first opportunity to address this issue. Thus, the amendments were not presented earlier because the need for the amendments was not apparent until the Final Office Action was received. Under these circumstances, entry of the amendments is permitted under § 1.116 and is respectfully requested.

These amendments introduce no new matter. Claims 88 and 90 have been amended to recite that the "polypeptide is not cyclized." The specification is replete with support for polypeptides that are not cyclized. In particular, the specification defines a polypeptide as "a polymer of amino acids, and unless otherwise limited, includes atypical amino acids that can function in a similar manner to naturally occurring amino acids." Applicants' specification, page 10, lines 19-21. Thus, polypeptides of the invention are not limited to a particular conformation. The specification states that "[p]olypeptides of the invention can be . . . modified to produce derivatives that retain the ability to induce differentiation fibroblasts to myofibroblasts" and goes on to discuss various modifications including cyclization. Applicants' specification, page 28, line 10 to page 30, line 4. One skilled in the art readily appreciates, from this description, that polypeptides of the invention can be the usual linear polypeptides or, in particular embodiments, can be cyclized. Table 3 (page 27) shows polypeptides having the sequences specifically recited in claims 88 and 90

in linear (i.e., non-cyclized) form. In addition, the techniques for synthesizing polypeptides of the invention described at page 33, line 13 to page 34, line 32 of the specification produce linear polypeptides, as do the recombinant techniques discussed at page 35, lines 1-18. Accordingly, the specification provides ample support for the amendment of claims 88 and 90.

### **35 U.S.C. §112, FIRST PARAGRAPH.**

#### **Written Description**

Claims 7, 8, 92, 93, 97, 98, and 100-103 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action, page 2. The only pending rejected claim is claim 92, and the rejection is traversed with respect to this claim.

The rejection was based on the recitation in formerly pending claim 7 that the recited IL-8 fragment “is no greater than about 8 amino acids in length” and in formerly pending claim 8 that the fragment “is no greater than about 15 amino acids in length.” See Office Action, page 3. Claim 92 previously recited: “A composition comprising the polypeptide of claim 7, 8, 88, or 90 and a pharmaceutically acceptable carrier.” Accordingly, the only reason for the rejection of claim 92 was its dependence from claims 7 and 8. Notably, claims 88 and 90 were not rejected for failure to comply with the written description requirement. As claim 92 has been amended to depend solely from claims 88 and 90, the rejection has been overcome. Withdrawal of the rejection is therefore respectfully requested.

#### **Enablement**

Claims 7, 8, 88, 90, 92, 100, 101, and 103 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Office Action, page 5. This rejection is moot as to cancelled claims 7, 8, 100, 101, and 103, and traversed as to claims 88, 90, and 92.

Claims 88 and 90 relate to polypeptides, and claim 92 relates to a pharmaceutical composition comprising these polypeptides. The rejection is based on the Examiner’s contentions that the “claims encompass polypeptides comprising IL-8 fragments which are cyclic” and that the “specification fails to teach or provide working examples, which demonstrate that IL-8 cyclic fragment peptides stimulate differentiation of fibroblasts to myofibroblasts.” *Id.* at 5. In the interest of expediting prosecution, Applicants have amended the pending claims to recite that the

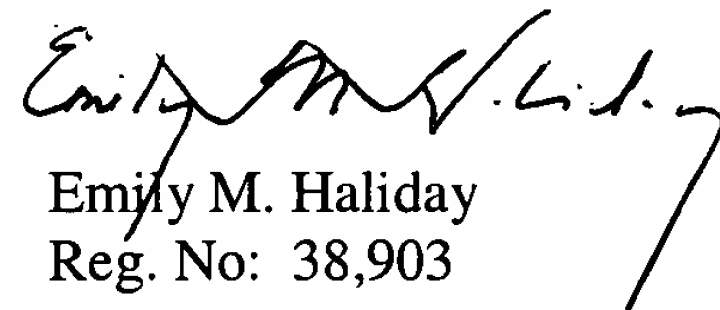
"polypeptide is not cyclized." This element is recited in claims 88 and 90 and incorporated into claim 92 by virtue of its reference to the polypeptide of claims 88 or 90. As the pending claims now exclude cyclic polypeptides, the alleged failure of the specification to enable such polypeptides is irrelevant. Accordingly, Applicants respectfully request withdrawal of the enablement rejection.

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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Respectfully submitted,

  
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